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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,676	08/16/2001	Donald F. Weaver	NCI-006DV2	5947

959 7590 12/20/2004

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/932,676

Applicant(s)

WEAVER ET AL.

Examiner

Deepak Rao

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): Provisional obviousness-type double patenting rejection.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

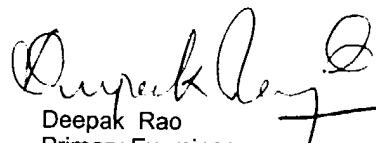
Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 01152004.
10. ☐ Other: _____


Deepak Rao
Primary Examiner
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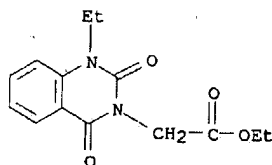
ADVISORY ACTION

An appeal under 37 CFR 1.191 was filed in this application on July 14, 2004. Appellant's brief is due on December 14, 2004 in accordance with 37 CFR 1.192(a).

Claim Rejections - 35 USC § 103

The remarks/arguments have been considered but they are deemed to be sufficient to overcome the rejection under 35 U.S.C. 103(a) because as explained in the previous office action, the reference teaches quinazoline-2,4-dione compounds and suggests structural analogs of the compounds. The reference teaches that the disclosed compounds induced convulsion due to their anticonvulsant activity. The instant claims exclude the reference disclosed compounds from the genus recited in the claims, however, include compounds that are structural analogs or homologs of the reference compounds which would have been obvious to one having ordinary skill.

For example, the reference discloses 1-ethyl-2,4-dioxo-1,4-dihydro-2H-quinazolin-3-yl)-acetic acid ethyl ester (depicted below for convenience)

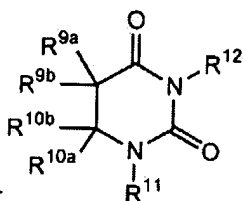


and the instantly recited genus includes a compound having a propyl group (-CH₂-CH₂-CH₃) in place of the ethyl group (-CH₂-CH₃), i.e., differs by a -CH₂ group. Compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups are generally of sufficiently close structural similarity that there is a presumed expectation that such

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compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Applicant argues that ‘it is unclear how the entire genus of the instant claims is a homolog of the limited number of prior art species’. The genus recited in the instant claims (depicted below for convenience)



includes compounds that are structurally homologous to the reference disclosed compounds. For example, R^{11} in the above genus is defined as alkyl, which includes the groups methyl, ethyl, propyl, etc. and therefore, includes the structural analog of reference disclosed compound. Applicant cites MPEP § 2144.09 and argues that ‘a genus structure which is not confined to adjacent homologs is not prima facie obvious in light of prior art species’. However, the MPEP section relied upon indicates that “prior art disclosure of C_8 to C_{12} alkyl sulfates was not sufficient to render prima facie obvious claimed C_1 alkyl sulfate”. Contrary to the explanation provided in the MPEP, the instant situation involves a claimed genus that includes an adjacent homolog of the reference disclosed compound (e.g., propyl in place of ethyl).

Applicant next reminds the examiner of the *Graham v. Deere Co.* requirements in establishing an obviousness rejection under 35 U.S.C. 103(a). The rejection was made fully taking into consideration of the above requirements as set forth in MPEP § 2144.08, which are further explained below:

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(A) Determine the scope and content of the prior art: The reference teaches quinazoline-2,4-dione compounds I having anticonvulsant activity and further, expressly discloses specific quinazoline-2,4-dione compounds, see the compounds disclosed in the reference.

(B) Ascertain the differences between the prior art and the claims in issue: The genus recited in the instant claims includes compounds that are structural analogs of the reference compounds, e.g., includes a compound that differs from the reference compound by a $-\text{CH}_2$ group.

Particularly, the instantly claimed genus includes a compound having a propyl substituent at the 1-position as compared to the reference disclosed ethyl group, which compound is a structural homolog of the reference disclosed compound.

(C) Determine the level of skill in the pertinent art: One of ordinary skill in the art would have had the reasonable expectation that such structurally analogous compounds would have similar properties and therefore, the same use.

In light of the above *Graham v. Deere* factors, the structural analogs of the reference compounds would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art would have been motivated to prepare the structural analogs of the reference compounds with the reasonable expectation that such compounds would have anticonvulsant activity. Therefore, it has been held that the claimed method using compounds that are structurally analogous to the reference disclosed compounds is prima facie obvious, absent a showing of unexpected results.

Applicant next argues that 'the five species disclosed in the reference are removed from the scope of the claims by proviso and therefore, the ordinary skilled artisan would not have been in the possession of the entire claimed invention'. As submitted by the applicant, the reference

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teaches five compounds which have been excluded from the genus of the instant claims.

However, the claimed genus includes compounds that are structural analogs of the reference disclosed compounds, which would have been suggested to one of ordinary skill in the art. It is to be noted that rejection under 35 U.S.C. 103 is proper where the subject matter claimed "is not *identically* disclosed or described" in the prior art, and the prior art directs those skilled in the art to the compounds, without any need for picking, choosing, and combining various disclosures. See *In re Shaumann et al.*, 572 F.2d 312, 315, 316, 197 USPQ 5, 8, (CCPA 1978). Further, the reference teaches that the compounds are useful as anticonvulsant agents, which is sufficient to one of ordinary skill to make the claimed compounds because similar properties are normally presumed when compounds are very close in structure. "The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made."

"Structural relationships provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." See *In re Duel*, 51 F.3d at 1558, 34 USPQ2d at 1214. The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). Reference must be

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considered, under 35 U.S.C. 103, not only for what it expressly teaches but also for what it fairly suggests, in determining obviousness. *In re Burckel*, 201 USPQ 67 (CCPA 1979).

For all the above reasons, the rejection for claims 88-90 under 35 U.S.C. 103(a) of the previous office action is hereby maintained.

Request to withdraw finality:

Applicant's request to withdrawn finality of the previous office action is considered but it was not found to be persuasive. Applicant amended the claims to overcome the rejection under 35 U.S.C. 102(b) of the first action on merits, which necessitated the obviousness rejection under 35 U.S.C. 103(a) applied in the final rejection. Prior to the amendment, the claims as presented were clearly upatentable as being anticipated by the teachings of the reference. A 35 U.S.C. 102/103 combination or cumulative rejection was not deemed necessary in the first office action because the claimed subject matter was disclosed in sufficient specificity in the reference to constitute anticipation under the statute.

The following rejection is withdrawn:

The obviousness-type double patenting rejection over copending application S.No. 09/932,677 is hereby withdrawn in view of applicant's remarks.

Receipt is acknowledged of the Information Disclosure Statement filed on January 15, 2004 and a copy is enclosed herewith.

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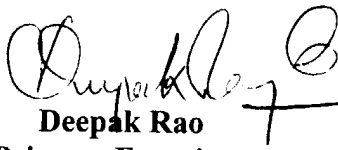
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

December 15, 2004